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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,293	10/23/2000	Stephen T. Kuehn	S16.12-0101	1653

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EXAMINER

NGUYEN, VI X

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 09/694,293	Applicant(s) KUEHN ET AL.	
	Examiner Victor X. Nguyen	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7,10-13 and 30-33 is/are pending in the application.
 4a) Of the above claim(s) 2,6,8,9,14,16,17,19,21,22,27 and 29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18,20,23-26 and 28 is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7,10-13 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The request filed on 1/6/2006 for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/694293 is acceptable and a RCE has been established. An action on the RCE follows.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-5,7,10-13 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Krueger et al (5,578,076).

Krueger et al disclose in Figs.1-2, a heart valve fastener (10) having the limitations as recited in claims 1 and 3, including: one pair of arms (16), where arms pivot from one orientation to a gripping position with ends of the paired arms being directed toward each other (at best seen in fig. 2 where the curved segment 74 is capable of being directed toward the curved segment 76. Regarding the intended use of the pair of arms are sized and adapted for fastening two adjacent tissue heart valve leaflets, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the arms of Krueger would have been capable of performing the use as claimed. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA

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1963). As to claims 4-5,7,10-13, a system further has a catheter or a trocar (see col. 2, lines 63-67, col. 3, line 1 and col. 4, lines 14-18) that is inherently capable for deployment into a human heart, where the paired arms (16) extend toward each other when the fastener is in a gripping position, and where the arms flex to a low profile position to fit within the catheter, where the fastener further has a shaft (60) that is releasably holding the fastener of the shaft

Regarding claims 30-33, Krueger et al disclose in Fig. 18, where a fastening member comprises a cap (370) and a gripper (366) comprises a plurality of arms (374) from a pivot (372), where each arm has a spike (376), and where the cap comprises a locking mechanism to lock the gripper in a lock position (see col. 6, lines 41-51), and where the fastener further has a flexible rod (125) which has a disengaging mechanism (fig. 5) which permits the rod to releasably holding the cap.

Allowable Subject Matter

3. Claims 18,20,23-26 and 28 are allowed.

The following is a statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses or suggests where a heart valve repair instrument comprising a cap that is located distal to the pivot and the pivot is located distal to a shaft, where a flexible rod connects to the cap to provide for movement of the cap relative to the pivot of the gripper and the shaft by pulling the flexible rod, where the cap has an opening that can be positioned over the pivot to lock the arms in a closed position.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Arguments

4. Applicant's arguments filed 11/7/2005 with regard to a heart valve leaflet fastener comprising at least one pair of arms, the pair being sized and adapted for fastening two adjacent tissue heart valve leaflets has been considered but are still deemed nonpersuasive because as set forth in the last Office Action, page 2, dated 7/7/2005. For example: it is noted that Krueger et al disclose in Figs.1-2, a heart valve fastener (10) including: one pair of arms (16), where arms pivot from one orientation to a gripping position with ends of the paired arms being directed toward each other (at best seen in fig. 2 where the curved segment 74 is capable of being directed toward the curved segment 76. Regarding the intended use of the pair of arms are sized and adapted for fastening two adjacent tissue heart valve leaflets, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the arms of Krueger would have been capable of performing the use as claimed. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In response to applicant's argument that Krueger reference does not disclose every element of claim 30. The examiner, respectfully, disagrees. As claim 30 is currently written, it can be interpreted broadly that the Krueger reference at least discloses in Fig.

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18, where a fastening member comprises a cap (370) and a gripper (366) comprises a plurality of arms (374) from a pivot (372), where each arm has a spike (376), and where the cap comprises a locking mechanism to lock the gripper in a lock position (see col. 6, lines 41-51).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen
Examiner
Art Unit 3731

Vn *VX*
2/9/2006

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER